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| 10/085,539      | 02/26/2002  | Wenda Carlyle        | PA872               | 9853             |

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EXAMINER

WEBMAN, EDWARD J

ART UNIT PAPER NUMBER

1616

DATE MAILED: 05/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/085,539

Applicant(s)

CARLYLE ET AL.

Examiner

Edward J. Webman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-7,9,11 and 21-25 is/are pending in the application.
- 4a) Of the above claim(s) 23 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-7,9,11,21,22 and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 5/7/02, 7/24/02, 6/23/03
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

RD

Applicant's election with traverse of Group I, a stent and rosiglitazone in the reply filed on 9/21/04 is acknowledged. The traversal is on the ground(s) that the method of Group II can not be practiced without the drug and that the elected species are equivalent to the other claimed devices and therapeutic agents. This is not found persuasive because applicants have cancelled claims directed to the nonelected groups and species, rendering the issue moot.

The requirement is still deemed proper and is therefore made FINAL.

Applicant's election without traverse of polycaprolactone in the reply filed on 1/28/05 is acknowledged.

Claim 22 is generic to a plurality of disclosed patentably distinct species comprising additional therapeutic agents. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with A. Kruegner on 5/12/05 a provisional election was made with traverse to prosecute the invention of rapamycin analogs, claim

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22. Affirmation of this election must be made by applicant in replying to this Office action. Claims 23 and 25 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 5-7, 9, 11, 21, 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy et al in view of Dasseux and Zenke et al.

Hassainy et al teach coated stents (title). Reducing the incidence of restenosis is disclosed (column 1 lines 16-20). Polycaprolactone is specified (column 4 lines 22-24). Vascular stents are disclosed (column 14 lines 11-13). Delivery of therapeutic agents in the coating is specified (column 7 lines 56 et seq.) Rapamycin as an immunosuppressive is disclosed (column 8 line 32). Mixing one or more therapeutic agents in the coating is specified (column 8 lines 36-38).

Dasseux teaches drug coated stents to reduce the risk of restenosis (abstract, column 117 lines 1-4). Rosiglitazone is specified (column 121 line 64).

Zenke et al teach that the 40-O-(2-hydroxyethyl) derivative or rapamycin has improved pharmacokinetic properties (column 1 lines 50-53).

It would have been obvious to one of ordinary skill to add rosiglitazone to the coated stent of Hassainy et al to achieve the beneficial effect of an additional agent to

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reduce the incidence of restenosis in view of Dasseux and to replace rapamycin with the 40-O-(2-hydroxyethyl) derivative to achieve the beneficial effect of its improved pharmacokinetic properties in view of Zenke et al.

Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 25 "derivative" has no antecedent in claim 22. Is "analogue" intended? Further "40-O" is indefinite. Is "40-O" intended?

No claims allowed.

Any inquiry concerning this communication should be directed to Edward J. Webman at telephone number 571-272-0633.

  
EDWARD J. WEBMAN  
PRIMARY EXAMINER  
GROUP 1500